



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of

: **Confirmation No. 4824**

Michael ROREGER

: Docket No. 96_0842A

Serial No. 08/737,111

: Group Art Unit 1617

Filed October 25, 1996

: Examiner Edward J. Webman

COLLAGEN PREPARATION FOR THE CONTROLLED
RELEASE OF ACTIVE SUBSTANCES

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REQUEST FOR RECONSIDERATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is responsive to the Official Action dated August 25, 2003.

Reconsideration is respectfully requested in view of the following remarks.

Claims 16-30 are rejected under 35 USC 102 as anticipated by Cioca. This ground of rejection is respectfully traversed.

Cioca discloses collagen preparations of macromolecular reconstituted collagen. The average molecular weight of collagen prepared in accordance with the Cioca patent is in the range of 383,000 to 460,000 (col. 4, lines 19-21).

Cioca teaches that the collagen is finally dissolved in an aqueous acid solution having a pH of 3-4 (col. 3, lines 44-53). Hence, these collagen preparations are acid-soluble and, therefore, chemically different from the collagen fractions of the present invention (see present specification, examples 1.1 and 1.2: "...dispersion in H₂O (ph 6.0)...insoluble collagen..."). Claims 16 and 24 both recite "acid-insoluble collagen".

Furthermore, Cioca fails to teach a collagen preparation which comprises a mixture of collagen fractions, each fraction having a different molecular weight. Cioca only discloses

preparations which are produced by combining a single collagen fraction with an active substance. In Cioca's Examples II and III, an active substance is added to a collagen solution obtained by the process described in Example I. This collagen solution is not described as a mixture of two or more fractions having different average molecular weights; rather, it represents a single fraction of collagen having only one average mol. weight (450,000; col. 6, lines 6-7).

While it is true that this preparation contains various molecular species of collagen (with molecular weight ranging from 30,000 to 1,500,000), this preparation comprises only one fraction with one average mol. weight. The average mol. weight of various collagen preparations thus obtained may range from 383,000 to 460,000 (col. 4, lines 19-25). However, as noted before, Cioca does not teach a preparation which comprises a mixture of various collagen fractions differing with respect to their average molecular weight. This would not make much sense, as the average molecular weights of Cioca's collagen fractions are in a rather narrow range (383,000 to 460,000) and can hardly be described as "different". In contrast, the present invention (in Examples 1 and 2) describes mixtures of collagen fractions having average mol. weights of 2,500,000 or 420,000, respectively. The advantages gained by the use of such mixtures are described on pp. 7-9 of the present specification. These advantages are impossible to achieve when using the preparations described by Cioca.

In summary, the collagen preparations of the present invention are chemically different from the collagen preparations described by Cioca, as they are acid-insoluble. They are also different from the Cioca disclosure since they comprise a mixture of different collagen fractions having different average molecular weights. Therefore, the rejection under 35 USC 102(b) should be withdrawn. The same applies with respect to process claim 24 which also refers to the collagen preparations of claim 16, and to the method claims 28-30 which are dependent on claim 16.

Favorable reconsideration and allowance is respectfully solicited.

Respectfully submitted,

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